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PLEASE NOTE: This document is updated as new information becomes available.

Vaccine Development and Approval

1) Is there a vaccine that protects against COVID-19 (SARS-CoV-2)?

Yes. Currently, there are two vaccines available to prevent COVID-19. The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved products (Pfizer-BioNTech and Moderna's COVID-19 vaccines) for active immunization to prevent COVID-19 in individuals 16 years of age and older in the United States.

Several other COVID-19 vaccines are in clinical trials but have not been approved. Some of these vaccines are currently being manufactured at the same time that clinical trials are occurring, so if approved for distribution, doses are available. If not approved, manufactured doses will be discarded.

2) When can we expect a vaccine to be available?

The Pfizer vaccine became available in North Dakota starting December 14th. The Moderna vaccine will be available the week of December 21st. Early on, vaccines will be limited to certain priority groups.

For the most up-to-date information, please visit the NDDoH [website](#).

A COVID-19 pipeline tracker is available [online](#).

3) Why is this COVID-19 vaccine development timeline so condensed compared to when other vaccines are licensed?

Some of the approaches that are being employed to shorten the timeline ***without sacrificing quality and safety*** include:

- Utilizing existing technology – many of the methods for producing a COVID-19 vaccine were previously being developed and explored for other vaccines.
- Developing vaccines immediately after viral genome sequence is available.
- Financing – The federal government has provided financing for COVID-19 vaccine development.
- Manufacturing – While completing the large phase III clinical trials, manufacturers can begin producing the vaccine, so that if it is shown to be safe and effective, they will have large numbers of doses ready. This is not typical because if the vaccine does not work, the manufacturer will have spent a significant amount of money to produce something that needs to be thrown away.
- Support efforts – While waiting for a vaccine to be ready, many other aspects of vaccine delivery can be prepared, including:
 - Developing plans for how to distribute the first, limited quantities that will be available

- Ensuring adequate supplies for distributing and administering vaccine, like vaccine vials, syringes and other equipment needed to vaccinate
- Establishing mechanisms for distribution to large subsets of the population

An explanation of how the process has been shortened is available from [Operation Warp Speed](#).

4) The development and production of a COVID-19 vaccine has been called “Operation Warp Speed”, does this mean shortcuts have been taken?

Operation Warp Speed is a partnership between the U.S. Department of Health and Human Services, the U.S. Department of Defense, and the private sector. The goal of Operation Warp Speed is to accelerate the development, manufacturing, and distribution of COVID-19 vaccine.

The Food and Drug Administration (FDA) has a well outlined regulatory process that assures any licensed vaccine has gone through a rigorous process to assure that it meets a standard for safety and efficacy before being released. All COVID-19 vaccine candidates being studied in the U.S. are in the process of completing these rigorous studies with no compromises in the process.

What has been significantly shortened (i.e. the “warp speed”) is the production process. The federal government has decided to fund the production of the leading vaccine candidates at the same time they are undergoing studies to assure their safety and efficacy. Should the vaccine candidate meet the FDA’s safety and efficacy requirements, supplies would then be ready to start immunizing right away.

A summary of Operation Warp Speed’s Strategy and Approach is found in the [New England Journal of Medicine](#).

5) What types of COVID-19 vaccines are in clinical trials?

According to the Children’s Hospital of Philadelphia’s [Vaccine Education Center](#), several approaches to COVID-19 vaccines are currently being tested. They include both tried-and-true as well as new approaches.

Here is a brief summary of these different strategies:

- Inactivated vaccine — The whole virus is killed with a chemical and used to make the vaccine. This is the same approach that is used to make the inactivated polio (shot), hepatitis A and rabies vaccines.
- Subunit vaccine — A piece of the virus that is important for immunity, like the spike protein of COVID-19, is used to make the vaccine. This is the same approach that is used to make the hepatitis B and human papillomavirus vaccines.
- Weakened, live viral vaccine — The virus is grown in the lab in cells different from those it infects in people. As the virus gets better at growing in the lab, it becomes less capable of reproducing in people. The weakened virus is then used to make the vaccine. When the weakened virus is given to people, it can reproduce enough to generate an immune response, but not enough to

make the person sick. This is the same approach that is used to make the measles, mumps, rubella, chickenpox and one of the rotavirus vaccines.

- Replicating viral vector vaccine — In this case, scientists take a virus that doesn't cause disease in people (called a vector virus) and add a gene that codes for, in this case, the coronavirus spike protein. Genes are blueprints that tell cells how to make proteins. The spike protein of COVID-19 is important because it attaches the virus to cells. When the vaccine is given, the vector virus reproduces in cells and the immune system makes antibodies against its proteins, which now includes the COVID-19 spike protein. As a result, the antibodies directed against the spike protein will prevent COVID-19 from binding to cells, and, therefore, prevent infection. This is the same approach that was used to make the Ebola virus vaccine.
- Non-replicating viral vector vaccine — Similar to replicating viral vector vaccines, a gene is inserted into a vector virus, but the vector virus does not reproduce in the vaccine recipient. Although the virus can't make all of the proteins it needs to reproduce itself, it can make some proteins, including the COVID-19 spike protein. No currently licensed vaccines use this approach.
- DNA vaccine — The gene that codes for the COVID-19 spike protein is inserted into a small, circular piece of DNA, called a plasmid. The plasmids are then injected as the vaccine. No currently licensed vaccines use this approach.
- mRNA vaccine — In this approach, the vaccine contains messenger RNA, called mRNA. mRNA is taken up in cells and then the cell processes it to make proteins. Once the proteins are produced, the immune system will recognize them and make a response against them to create immunity. In this case, the protein produced is the COVID-19 spike protein. No currently licensed vaccines use this approach.
 - ***The Pfizer and Moderna vaccines are both mRNA vaccines.***

For more information on the most recent updates on COVID-19 vaccines being developed, undergoing clinical trial, and approved/authorized for use, please see [The New York Times Coronavirus Vaccine Tracker](#).

6) How does the size of COVID-19 vaccine clinical trials compare to clinical trials for other vaccines routinely used in the United States?

According to an [article](#) published in *Human Vaccines and Immunotherapeutics* in 2012, phase III clinical trials for vaccines currently being used in the United States included, on average, 29,844 participants. Ongoing phase III clinical trials for COVID-19 vaccine include or plan to include at least 30,000 participants.

At the October Advisory Committee on Immunization Practices (ACIP) meeting, the number of participants in clinical trials and diversity of participants were [presented](#).

7) Are people from different races and ethnicities being included in clinical trials for COVID-19 vaccines?

Yes. Vaccine manufacturers have made special effort to ensure clinical trials are inclusive of people from different races and ethnicities. Both Pfizer and Moderna, two of the manufacturers of COVID-19 vaccines in late stage clinical trials, are reporting at least 30% of participants being from diverse backgrounds (Black, Hispanic, Asian, American Indian). At the October ACIP meeting, the number of participants in clinical trials and diversity of participants were [presented](#).

8) What will be needed to license a COVID-19 vaccine in the United States?

Vaccine manufacturers must follow guidance provided by the FDA while developing any COVID-19 vaccine. This includes requirements to share information about how they determined that a vaccine is safe and effective. They will need to provide data for review and information, so the FDA and other scientists can understand how the studies were designed, how many people were evaluated, and how the testing to obtain the data was done. It is likely that at first, COVID-19 vaccine(s) will not be fully licensed (Biological License Application) but will receive emergency use authorization.

9) What is Emergency Use Authorization?

During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives. It is likely that a COVID-19 vaccine will be made available using an EUA.

The FDA has established strict safety and efficacy [criteria](#) in order for a vaccine to be approved through EUA. Criteria includes two months post vaccination data, minimum clinical trial size, at least a 50% effectiveness and a certain number of severe COVID-19 cases in participants. COVID-19 vaccines will also be reviewed by external, independent experts.

Additional information about EUA is available on FDA's [website](#).

10) Can you explain the difference between EUA and a Biological License Application (BLA)?

- An EUA is granted by the FDA and can be completed in a short amount of time (weeks). An EUA allows the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives. The FDA must determine, among other things, that the *known and potential benefits of a product outweigh its known and potential risks*.
- A BLA is also undertaken by the FDA but can take up to a year to complete. A BLA can only be approved if FDA determines there is *substantial evidence of safety and effectiveness* from adequate and well-controlled trials.
- Both EUAs and BLAs require data showing the vaccine is safe and effective.

- For both an EUA and a BLA, the FDA receives advisement from the Vaccines and Related Biological Products Advisory Committee (VRBPAC). VRBPAC is an external, expert committee (i.e. scientist, physicians, biostatisticians, and a consumer representative) that reviews and evaluates data concerning the safety, effectiveness and appropriate use of vaccines and related biological products.
- Because vaccines are given to millions of *healthy* individuals, the requirements for vaccine EUAs are much stricter than requirements for those drugs that have received EUA thus far during the COVID-19 pandemic for treatment of the ill.

11) Why might the FDA issue an EUA before a BLA for a COVID-19 vaccine?

- A vaccine for COVID-19 is most likely going to first be approved under EUA to promote more *rapid and widespread* deployment and administration of COVID-19 vaccine.
- A vaccine may be issued under an EUA with the *ultimate goal* of receiving a BLA.
- A vaccine issued under EUA will continue to be monitored and evaluated by multiple agencies in the United States (e.g. the Center for Disease Control and Prevention [CDC] and the FDA), to assure any vaccine authorized under EUA is safe and effective.

COVID-19 Vaccine Safety and Efficacy

12) Is the COVID-19 vaccine safety tested?

Yes. All COVID-19 vaccine candidates are being studied in large groups of people in order to ensure they are both safe and effective. After vaccines are approved for emergency use or full licensure, they will continue to be monitored for safety through the robust vaccine safety monitoring system in the U.S.

If a serious potential adverse event is noted during a clinical trial, that trial may be paused while that event is investigated. Because of high safety standards for vaccines, it's typical for most vaccine candidates to not make it to the final stages of testing. For COVID-19 vaccines in clinical trials, it is possible that not all vaccine candidates will come to market.

13) What is the current safety and efficacy of COVID-19 vaccines in clinical trials?

Pfizer and Moderna have both indicated that their COVID-19 vaccines are safe and effective.

Pfizer's COVID-19 vaccine showed no serious safety concerns, and there were no serious adverse events reported for Moderna's COVID-19 vaccine.

Pfizer reported 95% efficacy for those who received two doses, while Moderna reported 94.1% efficacy for those who received two doses.

Full safety and efficacy information is available in the FDA briefing documents ([Pfizer](#) and [Moderna](#)). Information from other clinical trials will be available and reviewed before vaccines are administered.

14) What is efficacy? Is there a difference between vaccine efficacy and effectiveness?

Vaccine efficacy and vaccine effectiveness measure the proportionate reduction in cases among vaccinated persons. The term vaccine “efficacy” is used when a study is carried out under ideal conditions, for example, during clinical trials. Vaccine “effectiveness” is used when a study is carried out under real-world conditions.

A COVID-19 vaccine with 95% efficacy means that it has the ability to *prevent* 19 out of 20 COVID-19 infections in *those who are vaccinated*. In other words, the vaccinated group experienced 95% fewer COVID-19 cases than they would have if they had not been vaccinated.

15) How does the efficacy of the Pfizer and Moderna vaccines compare to other vaccines?

Both the Pfizer and Moderna vaccines’ efficacy is among the best we have available compared to routinely recommended vaccines. For example, compare the efficacy of COVID-19 mRNA vaccines to other routinely recommended vaccines:

- Pfizer novel coronavirus vaccine (2 doses): 95%
- Moderna novel coronavirus vaccine (2 doses): 94.1%
- Influenza vaccine (1 dose): ~44%
- Chickenpox/Varicella vaccine (2 doses): 90%
- Measles (MMR-2 doses): 97%

16) What is the efficacy of the COVID-19 vaccine if I only receive one dose?

Pfizer has indicated that the efficacy of their COVID-19 vaccine after one dose is at least 52%. Moderna has noted 80.2% efficacy after one dose. For best protection, it is recommended that individuals receive two doses.

17) Is it true that people in the COVID-19 vaccine clinical trials died?

According to data released by Pfizer and Moderna, clinical trial participants did pass away during the safety monitoring period following vaccination. However, it is important to note that the **deaths that occurred in the vaccinated group were not caused by the vaccination.**

In the [Pfizer](#) briefing document for Emergency Use Authorization, six deaths were noted in the study population; 2 in the vaccine group and 4 in the placebo group (placebo group = those who did not get the vaccine). In the [Moderna](#) briefing document for EUA, 13 deaths were noted; 6 in the vaccine group and 7 in the placebo.

- For those in the vaccine group, none of the deaths were related to vaccine administration.
- **The rate of deaths in the study group occurred at a similar rate to that which would be expected in the general population.**

18) How will safety of the COVID-19 vaccine be monitored?

COVID-19 vaccine safety will continue to be monitored after a vaccine is made available to the public. The [Vaccine Adverse Events Reporting System](#) (VAERS) will be used to identify signals that might indicate a safety issue. The [Vaccine Safety Datalink](#) (VSD) will also be used. VSD is an active surveillance system that monitors electronic health data for adverse events in various healthcare settings. The [Clinical Immunization Safety Assessment Project](#) (CISA) will conduct clinical research and assess complex vaccine safety issues. A new, additional safety monitoring program, V-SAFE, is also planned to monitor COVID-19 vaccines using smartphones for health surveys. Additional information about safety monitoring is available on [CDC's COVID-19 vaccine website](#).

19) Is the COVID-19 vaccine being studied in children or pregnant women?

Recently, [Pfizer](#) started to include children in COVID-19 vaccine clinical trials. Moderna has also announced that they will begin enrolling children. The vaccine was not specifically studied in pregnant women. Before vaccines are studied in pregnant women, developmental and reproductive toxicity (DART) studies, which use animal models, are conducted to ensure safety of vaccines in pregnant women. Pfizer DART studies are currently underway and results are expected in the near future. Moderna's DART studies found no safety concerns in pregnant animals.

20) If vaccine trials do not include people with autoimmune conditions, how will we know if they can be vaccinated?

The requirements related to who can participate in a vaccine trial vary based on the company running them, the disease they are seeking to protect against, and various types of autoimmune conditions. Often the first studies are the most restrictive, so that the data are not influenced by other conditions. Later scientists and healthcare providers will accumulate data for different sub-groups. In some cases, specific trials will be conducted, but often the information on healthy adults can inform what to expect regarding different conditions. About half of the people participating in clinical trials are considered high-risk for COVID-19.

21) Do COVID-19 vaccines cause people to faint?

Fainting, also called syncope, is a common event surrounding vaccination. It is not caused by a vaccination itself; fainting is thought to be caused by the vaccination process (ex. anxiety associated with vaccination). Fainting is usually not serious and has no long-lasting effects.

Because fainting is a common occurrence for vaccinated individuals, we expect to hear reports of individuals who faint when they receive their COVID-19 vaccine. Fainting is not a sign of a vaccine reaction. To help minimize the risks associated with fainting, everyone who receives a COVID-19 vaccine is recommended to be monitored for 15 minutes following vaccination.

22) Will the mRNA COVID-19 vaccines alter your DNA?

No, **mRNA vaccines cannot alter DNA**. The mRNA vaccines work by introducing a messenger RNA molecule into your body, which causes cells to produce a protein that resembles one of the viral proteins that make up SARS-CoV-2. Your immune system recognizes the viral protein and generates an immune response against it.

The mRNA vaccines are unable to change your genetic makeup because the mRNA injected into the tissue to stimulate an immune response **does not integrate into the cell nucleus of its recipients, thus genetic modification is not possible**. It only presents the body with the instructions to build a protein, which builds immunity. When the cells divide, they will only include your natural DNA. Further, the time RNA survives in the cells is relatively brief, usually only a span of hours.

23) I've heard that COVID-19 vaccines were developed to control the population through microchip tracking. Is this true?

No. There is no vaccine microchip, and the vaccine will not track people. This myth started after comments made by Bill Gates about a digital certificate of vaccine records. The technology he was referencing is not a microchip, has not been implemented in any manner and is not tied to the development, testing or distribution of COVID-19 vaccines.

24) Can I receive the COVID-19 vaccine if I am allergic to latex?

Yes. People with a latex allergy can receive the COVID-19 vaccine. There is no latex in the vaccine and the vaccine vial's rubber stopper does not contain latex.

It is still important to let your healthcare provider know about any latex allergies so they can ensure they do not use any latex containing products (ex. gloves) when administering the vaccine.

25) I heard reports of anaphylaxis following receipt of the Pfizer COVID-19 vaccine. Should I be concerned about an allergic response from the vaccine?

Anaphylaxis is an acute and potentially life-threatening serious allergic reaction that rarely follows vaccination. There have been some reports of anaphylaxis following receipt of Pfizer's COVID-19 vaccine. The CDC is investigating these reports and will update vaccine recommendations as more information becomes available.

The Pfizer vaccine was studied thoroughly in clinical trials prior to receiving EUA. The phase 3 trial results indicated **that vaccine was generally well tolerated with no serious safety concerns reported**. However, it is possible for vaccines to cause allergic reactions. As quoted by Dr. Paul Offit, a vaccine expert, "Certainly, vaccines can cause severe allergic reactions. In the U.S., roughly one of every 1.4 million doses of vaccines is complicated by a severe allergic reaction." The CDC advises telling a

provider if you have any severe, life-threatening allergies before taking any vaccine, including the COVID-19 vaccine.

The FDA and CDC have included a history of severe allergic reactions to the COVID-19 vaccine or any COVID-19 vaccine ingredient as a reason not to receive the Pfizer vaccine.

Individuals who have a history of anaphylaxis to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) may receive a COVID-19 vaccination, but should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. They should also be monitored for 30 minutes following vaccination.

The CDC has posted guidelines for managing anaphylaxis at vaccination sites [here](#).

26) I heard the head of Pfizer research said the vaccine could cause female sterility? Is this true?

This claim is false. Experts say there is no evidence that the Pfizer vaccine would result in sterilization of women.

If you look into the original claim on social media, you will discover it is full of misinformation.

- First, the person who made the claim is not the head of Pfizer research. **The truth:** the individual worked at Pfizer nearly a decade ago in a division that was not directly involved in vaccinology.
- Second, the claim says the COVID-19 mRNA vaccine produces a protein called syncytin-1, which is vital for placental formation. If the body creates an immune response to syncytin-1, the immune system may inadvertently attack the placenta during future pregnancies and lead to infertility. **The truth:** the vaccine works by forming an immune response to the SARS-CoV-2 spike protein. The SARS-CoV-2 spike protein does share a very small genetic sequence with syncytin-1. However, there is little concern about the possibility of the anti-spike protein antibodies attacking the syncytin-1 protein because the immune system recognizes the surface of target proteins, and this is rarely confined to a short genetic sequence (like the genetic sequence shared between the SARS-CoV-2 spike protein and syncytin-1).
- Finally, if this claim was true, those who have had natural infection with COVID-19 would also produce antibodies to the syncytin-1 protein and would experience infertility. Currently, we have no evidence that natural infection is leading to infertility in women.

27) Does the Pfizer COVID-19 vaccine cause Bell's palsy?

At this time, Bell's palsy does not appear to be associated with COVID-19 vaccination. In the Pfizer clinical trial data, four cases of Bell's palsy were noted in the vaccine group while zero cases were noted in the placebo group. In the Moderna clinical trial data, three cases were noted in the vaccine group and one case was noted in the placebo group. **The cases in the vaccine group do not represent a frequency above the rate of Bell's palsy that is expected in the general population.** Also, there is currently no evidence to conclude a causal relationship between vaccination and Bell's palsy. The FDA

will recommend surveillance for cases of Bell's palsy as the vaccine is administered to the general population to determine if vaccination is associated with increased risk of Bell's palsy.

28) Is the COVID-19 vaccine made with fetal cells?

- The mRNA COVID-19 vaccines produced by Pfizer and Moderna **do not require the use of any fetal cell cultures in order to *manufacture* the vaccine.**
- The following organizations assert that the mRNA COVID-19 vaccines are ***ethically uncontroversial***: [National Catholic Bioethics Center](#), [The Vatican - Congregation for the Doctrine of the Faith](#), [Pontifical Academy of Life Statement](#), [Charlotte Lozier Institute](#), [United States Conference of Catholic Bishops](#), the [North Dakota Catholic Conference](#) and the [Immunization Action Coalition](#).
- For more information on this topic please view the [NDDoH handout](#).

Getting Vaccinated

29) Who will get the vaccine first? Who has been identified as priority populations?

Early on, COVID-19 vaccine will be limited and need to be prioritized.

Priority groups for vaccination continue to be evaluated. At this time, the ACIP has decided on the following phases:

- Phase 1A: Healthcare workers and long-term care residents
- Phase 1B: Persons aged 75 years of age and older and frontline essential workers
- Phase 1C: Persons 65-74 years of age, persons aged 16-64 with high-risk medical conditions, and other essential workers

The federal Advisory Committee on Immunization Practices (ACIP) will make recommendations as to who should be prioritized for COVID-19 vaccine. Further, the North Dakota COVID-19 Vaccination Ethics Committee is currently developing priorities amongst the likely priority groups, as vaccine will be very limited to start and will need to be prioritized amongst ACIP priorities.

Please visit the NDDoH COVID-19 vaccine [website](#) for the most up-to-date information regarding priority groups.

30) Why was my group not considered in a higher tier in the priority groups?

Great consideration went into determining priority groups. The North Dakota Advisory Committee on COVID-19 Vaccination Ethics considered the following when determining priority groups:

- Risk and intensity of exposure to COVID-19
- Likelihood of adverse outcome if infected with COVID-19

- Critical role in ensuring survival of infected patients and ensuring the integrity of community function

In considering risk, many factors may fall under the above categories, including living in a congregate setting, known impact of the epidemic on a population, provision of direct or indirect patient care especially to persons at increased risk or known to have COVID-19, having underlying health conditions or being age 65 years or older. Separation of one group from another is often determined not just by the presence of a risk factor but by the number of factors each group has.

The committee recognizes that there is no one “right” answer, but some answers are better than others. ***Unfortunately, not everyone can be highest priority for vaccination.***

For more information on priority groups, please visit the CDC [website](#).

31) How many doses of COVID-19 vaccine are required to complete the vaccine series?

Pfizer

The Pfizer COVID-19 vaccine requires two doses separated by 21 days.

Moderna

The Moderna COVID-19 vaccine requires two doses separated by 28 days.

There are other COVID-19 vaccines currently in clinical trials. One vaccine requires only one dose, while others require two. It is important to know which vaccine you have received and when/if you need to return for additional doses.

32) Do I need to get the same vaccine to complete my two doses?

Yes. If you receive a vaccine product that requires two doses, the second dose must be the same brand/manufacturer as the first dose.

33) How will I know which vaccine product I received?

Each person will receive a vaccine record card that states the COVID-19 vaccine product that was administered and the date it was received. It is important to keep this card in a place where it will not be lost or misplaced in order to assure the second dose of COVID-19 vaccine is the same brand/manufacturer as the first dose received. Patients who are vaccinated are encouraged to take a picture of their immunization record card with their smartphone.

Doses will also be documented in the North Dakota Immunization Information System (NDIIS), so health care providers across the state will know which type of vaccine a patient received and when.

34) Will vaccine recipients be required to show their COVID-19 vaccination record card in order to get their second dose?

No, However, all vaccine recipients should be encouraged to keep their card and show it at their follow-up vaccination appointment.

35) When will there be enough vaccine for everyone who wants to be vaccinated to get a COVID-19 vaccine?

At this point, no one can really answer the question as to when everyone in the United States would be able to be vaccinated. It is possible that there may be enough vaccine in 2021 for anyone who wishes to be vaccinated to have access to COVID-19 vaccine.

36) When will essential workers be able to be vaccinated?

At this time, the [ACIP](#) recommends that COVID-19 vaccine be offered to Phase 1a priority groups, which includes 1) healthcare personnel and 2) residents of long-term care facilities, when vaccine becomes available.

Demand for COVID-19 vaccine is expected to exceed supply during the first months of the national COVID-19 vaccination program. The NDDoH will follow guidance from the ACIP when determining priority groups for vaccination. It is possible that the North Dakota COVID-19 Vaccination Ethics Committee may further prioritize priority groups in the essential workers category. If essential workers are included in Phase 1B or Phase 1C, it is possible that vaccination could begin in early 2021.

As priority groups are expanded, the NDDoH will update the public regarding who is eligible for COVID-19 vaccination. Updated information on COVID-19 vaccine and availability can be found on the NDDoH [website](#).

37) Where can I sign up for COVID-19 vaccination?

At this time, there is not a location to sign up for COVID-19 vaccination for the general public. Because supplies will be **very** limited when vaccine is initially available, only those in Phase 1a priority groups will be able to receive vaccine. Phase 1a includes: 1) healthcare personnel and 2) residents of long-term care facilities. But, as priority groups are expanded, the NDDoH will update the public regarding who is eligible for COVID-19 vaccination and how to get vaccinated. The NDDoH recommends visiting www.vaccinefinder.org to find a COVID-19 vaccine provider when your priority group is eligible for vaccination.

38) How will I be notified when I am able to be vaccinated?

The North Dakota Department of Health website and social media pages will be updated regularly to notify the public regarding who is eligible for COVID-19 vaccination.

39) What are common side effects after vaccination?

Common side effects from vaccination include pain, swelling or redness where the shot was given, a mild fever, chills, fatigue, headache, and muscle and joint aches. These side effects were also noted in COVID-19 vaccine clinical trials.

40) Is there anyone who should not be vaccinated with COVID-19 vaccine?

Do not administer COVID-19 vaccine to individuals with a known history of a severe allergic reaction (e.g. anaphylaxis) to a previous dose or any component of a COVID-19 vaccine.

41) Will people with underlying conditions be recommended to receive the vaccine?

Yes. People with underlying conditions are at a higher risk for severe COVID-19 disease. Vaccine may be administered to these individuals unless otherwise indicated. Phase 2 and phase 3 clinical trials demonstrated similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19.

42) Will people who are immunocompromised be recommended to receive COVID-19 vaccine?

Yes. These individuals may be at increased risk for severe COVID-19. They may receive COVID-19 vaccine unless otherwise indicated.

43) Will people who have had COVID-19 be recommended to receive the COVID-19 vaccine?

Yes. Vaccination should be offered to all eligible individuals, regardless of their history of prior symptomatic or asymptomatic SARS-CoV-2 infection.

There is not a minimum interval between infection and vaccination. However, current evidence suggests reinfection is uncommon in the 90 days after initial infection, and thus, persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired.

44) Should people who currently have COVID-19 be vaccinated?

Vaccination should be postponed until the person has recovered and criteria have been met to end isolation.

There is not a minimum interval between infection and vaccination. However, current evidence suggests reinfection is uncommon in the 90 days after initial infection, and thus, persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired.

45) Should people who are currently in quarantine present for vaccination?

No. People who are quarantined because of exposure to COVID-19 should wait to be vaccinated until their quarantine period has ended. This is to prevent spread to COVID-19 vaccinators.

46) Should individuals who have previously received passive antibody therapy for COVID-19 be vaccinated?

Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses.

47) Can pregnant women receive COVID-19 vaccine?

Yes. Pregnant women may choose to be vaccinated. They should weigh the risk of COVID-19 (i.e. healthcare workers) with the risks of vaccination. Pregnant women should discuss vaccination with their healthcare provider. The American College of Obstetrics and Gynecology has published guidance [here](#).

Considerations for vaccination include: 1) level of COVID-19 community transmission, 2) her personal risk of contracting COVID-19, 3) the risks of COVID-19 to her and potential risks to the fetus, 4) the efficacy of the vaccine, 5) the known side effects of the vaccine, 6) the lack of data about the vaccine during pregnancy.

Pregnant women who experience a fever following vaccination should be counseled to take acetaminophen, as fever has been associated with adverse pregnancy outcomes.

48) Can women who are breastfeeding receive COVID-19 vaccine?

Yes. Women who are breastfeeding may choose to be vaccinated. mRNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant. However, there are no data on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or milk production/excretion. The American College of Obstetrics and Gynecology has published guidance [here](#).

49) Can children be vaccinated against COVID-19?

Pfizer's COVID-19 vaccine has been recommended for adolescents 16 and 17 years of age. Emergency Use Authorization of the Pfizer vaccine does not include use in individuals younger than 16 years of age.

Moderna's COVID-19 vaccine is only approved for individuals 18 years and older.

50) What happens if I have a problem or bad reaction after getting a COVID-19 vaccine?

The CDC and FDA encourage the public and healthcare providers to report possible side effects (called adverse events) to the [Vaccine Adverse Event Reporting System](#) (VAERS). This national system is not designed to determine if a vaccine caused a health problem, but is especially useful for detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine.

CDC is also implementing a new smartphone-based tool called V-SAFE to check-in on people's health after they receive a COVID-19 vaccine. When you receive your vaccine, you should also receive a V-SAFE information sheet telling you how to enroll in V-SAFE. If you enroll, you will receive regular text messages directing you to surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.

51) Will I be able to get the COVID-19 vaccine at the same time as other vaccines?

COVID-19 vaccines should not be given at the same time as other vaccines. The CDC recommends a 14-day interval between COVID-19 vaccine and other vaccines.

52) How long will immunity from the COVID-19 vaccine last?

At this time we do not know how long immunity following vaccination will last. Pfizer noted that there **does not** appear to be evidence of waning protection during the follow-up time of approximately 2 months following the second dose of the vaccine.

What we do know is that COVID-19 vaccines will be continuously monitored to determine duration of immunity after vaccination. Immunity following vaccination will depend on which types of vaccines are licensed or authorized and what part of the immune system responds to the vaccine.

53) Will I need to get a COVID-19 vaccine annually like an influenza vaccine?

Currently, the answer is unclear. It is possible that over time, additional doses of vaccine may be needed to provide continued protection. It will take ongoing evaluation over several months and years to understand how our immune systems respond to this virus and COVID-19 vaccines.

54) Can a COVID-19 vaccine cause COVID-19?

No. None of the vaccines currently in development in the United States use the live virus that causes COVID-19. Vaccination with COVID-19 vaccine could cause side effects, such as fever and body aches. This is not COVID-19. These symptoms are normal after vaccination and are a sign the body is building immunity.

55) Can a COVID-19 vaccine cause you to test positive on COVID-19 viral tests?

No. COVID-19 viral tests are used to detect current infection. COVID-19 vaccines cannot cause COVID-19 infections.

56) Will getting the flu vaccine protect me against COVID-19?

No. Influenza viruses and coronaviruses are different, so the flu vaccine does not protect against coronavirus. This fall and winter, both COVID-19 and influenza will be circulating at the same time. Both are respiratory illnesses and have similar symptoms. Influenza vaccination will be important to prevent illness this fall and the burden of influenza illness on health care providers. Additionally, influenza vaccine will prevent you from being sick and having to miss work or school. While it may seem like there is so much out of our control during this pandemic, getting vaccinated against influenza is within our control. This will protect not only those who receive flu vaccine, but also the community.

57) Does the flu vaccine cause COVID-19?

No. The influenza vaccine does not contain the novel coronavirus or any coronaviruses. The influenza vaccine will not prevent or protect against COVID-19. Because the influenza vaccine does not contain the COVID-19 virus, it will not impact results of COVID-19 tests. The PCR test for COVID-19 is specific to COVID-19.

The influenza vaccine will help prevent the flu and serious complications due to influenza. A number of additional benefits from influenza vaccine can be found [here](#). Influenza vaccination will reduce the burden of illness on healthcare providers, including hospitals. Because influenza and COVID-19 are both respiratory illnesses, vaccination will also reduce the burden of disease and need for COVID-19 testing. Co-infection with COVID-19 and influenza in China led to more severe outcomes according to data presented at the [June Advisory Committee on Immunization Practices meeting](#). A large study in [Brazil](#) showed more COVID-19 deaths in people who were not vaccinated against influenza.

58) Is there an interval between influenza vaccination and receiving COVID-19 vaccine?

The CDC recommends a 14-day interval between COVID-19 vaccine and other vaccines, including influenza vaccines.

59) How much will the coronavirus vaccine cost?

At this time, coronavirus vaccines are expected to be distributed for free. It is possible that health care providers may charge a fee to administer the vaccine. Health insurance will cover these fees. Those who are uninsured and unable to pay the administration fee cannot be turned away.

60) If you had COVID-19 and recovered will you still be able or need to get the vaccine?

Yes. Vaccination should be offered to all eligible individuals, regardless of their history of prior infection.

61) Why should I get a COVID-19 vaccine?

The COVID-19 pandemic has had a significant impact on all of our lives. Although you may not know anyone who has been directly affected by the disease, it is ever-present in our community. Further, more than 1 in a 800 North Dakotans have died from COVID-19. While preventative measures like social distancing and masks help to slow the spread, ***the only truly preventive measure against this virus is to vaccinate.***

By vaccinating against COVID-19, you not only protect yourself, but also prevent spread of the disease to your friends, loved ones, and those in your community. COVID-19 can have serious, life threatening complications and there is no way to know how the virus will affect you. COVID-19 vaccines are being carefully evaluated and will be authorized only if they are found to be safe and make it substantially less likely you'll get COVID-19.

For more information on the benefits of getting a COVID-19 vaccine, please see the CDC [website](#).

62) If I get COVID-19 vaccine, do I still have to wear a mask or quarantine if I am exposed?

It is unknown at this time how effective the COVID-19 vaccine will be, so until additional information is available, even if you are vaccinated, you still need to take additional measures to prevent COVID-19. This includes social distancing, wearing a mask, and observing quarantine recommendations.

63) If one product has slightly higher efficacy than another vaccine, isn't it better to get the better vaccine with higher efficacy?

No. Any COVID-19 vaccine that is authorized for use in the United States has met the FDA's rigorous guidelines regarding EUA and has been reviewed by both VRBPAC and the ACIP (expert committees that provide recommendations and guidance on immunizations). In the last ten months, we have had over 250,000 deaths associated to COVID-19. While preventive measures like social distancing and masks help to slow the spread, ***the only truly preventive measure against this virus is to vaccinate.***

Preliminary data from Pfizer and Moderna is extremely promising. Phase III trial results on both vaccines indicate an efficacy around 95%, rivalling the effectiveness of some of the best vaccines available to us against other viruses, such as MMR (97% effective) and chickenpox (92% effective) vaccines. In addition, efficacy for the Pfizer and Moderna vaccine was consistent across age, gender, race, and ethnicity demographics. There is no reason to wait for a better vaccine when both the Pfizer and Moderna vaccines efficacy is among the best we have available compared to all recommended vaccines.

64) I have heard COVID-19 vaccine manufacturers are not liable for vaccine injury. What happens if I have a vaccine injury?

Serious adverse events from vaccination are ***extremely rare***. In the event of a serious injury following vaccination with COVID-19 vaccine, the PREP Act provides immunity from liability to the vaccine manufacturer, and the Countermeasures Injury Compensation Program (CICP) provides benefits to individuals who sustained the injury. More information on the PREP Act and CICP is below.

To encourage expedient development of medical countermeasures during a public health crisis, [the PREP Act](#) was created in 2005. The PREP Act authorizes the Secretary of the Department of Health and Human Services (HHS) to issue a PREP Act Declaration that provides immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency. Previous PREP Act declarations have been issued numerous times, including those for the H1N1 pandemic in 2009.

The PREP Act does provide manufacturers of countermeasures (i.e. COVID-19 vaccine) some immunity from liability, but **this does not mean COVID-19 vaccine injuries are not covered or compensated for**. They are covered under the [Countermeasures Injury Compensation Program](#) (CICP). The PREP Act authorizes CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures identified in and administered or used under the PREP Act declaration.

Although vaccine manufacturers are not liable for unforeseen adverse events, they would be liable for negligence.

For more information on the PREP Act, please see the Public Health Emergency [website](#).

For more information on CICP, please see the HRSA [website](#).

65) I have heard there is a new strain of coronavirus circulating in the U.K.. Will the COVID-19 vaccines provide protection against it?

It is unlikely the new virus strain (caused by a mutation) will affect the efficacy of a vaccine in the short term. It is possible a variant of the virus may someday make current vaccines ineffective, but chances of this happening are very low. The manufacturers anticipated potential mutation of the virus, as this is common in coronaviruses. Because of this knowledge, both Moderna's and Pfizer's vaccines target the entire spike protein on the surface of SARS-CoV-2. Vaccinated individuals produce antibodies that recognize many different parts of the spike protein, so even if one portion of the protein changes or mutates, there will be antibodies to other parts of the protein, which makes it harder for the virus to evade our immune systems.

66) What if I refuse a COVID-19 vaccine, will there be a penalty?

There will be no penalty for refusing a COVID-19 vaccine. **Yet, vaccinating is the only way to end the pandemic and begin the process of returning to normal life.** It is important to note that some employers may decide to not cover pay from quarantine and/or isolation required from COVID-19 exposure or infection if you refuse to vaccinate. Further, both the Pfizer and Moderna vaccines preliminary data indicate an efficacy around 95%, which places them among the best vaccines we have available compared to all recommended vaccines.

It is also important to consider the true risk of choosing not to vaccinate. By not vaccinating, you put yourself and those around you at risk of getting sick from COVID-19. This virus can have serious, life threatening complications and there is no way to know how the virus will affect you. COVID-19 vaccines are being carefully evaluated and will be authorized only if they are found to be safe and make it substantially less likely you'll get COVID-19. The best way to protect yourself and prevent spread of the disease to your friends, loved ones, and those in your community is to **vaccinate against COVID-19**.

For more information on the benefits of getting a COVID-19 vaccine, please see the CDC [website](#).

67) Will people traveling south this winter be able to get the vaccine in that state (i.e. Florida or Arizona)?

At this point, there will be a very limited supply when vaccines are initially available. Vaccine will be administered by priority groups. The first group designated by the ACIP in phase 1a includes healthcare workers and residents in long-term care facilities. If you are a seasonal traveler or "snowbird", when vaccine becomes available to your priority group, your geographic location will not alter your ability to get vaccinated. The NDDoH encourages individuals to use [VaccineFinder](#) to find a location that offers COVID-19 vaccine in your area and check with local health departments for instructions.

68) If I receive my first dose of COVID-19 vaccine in North Dakota, but will be traveling south to a winter residence, will I be able to receive my second dose in that state?

If you are a seasonal traveler or "snowbird" and have received your first dose of COVID-19 vaccine in North Dakota and have traveled south prior to receiving your second dose of vaccine, *it is important to keep your [Vaccination Record Card](#) with you.* The Vaccination Record Card will include important information on your first dose of COVID-19 vaccine including which vaccine you received, when you received it, and where you received it. If you have traveled to a winter home between doses, the NDDoH encourages individuals to use [VaccineFinder](#) to find a location that offers COVID-19 vaccine in your area and check with local health departments for instructions.

69) Will COVID-19 vaccine be mandated in North Dakota?

COVID-19 vaccine will not be mandated for all North Dakotans. The unique nature of COVID-19 vaccine being available under EUA (rather than full FDA licensure) when it will first be available is unprecedented.

The Equal Employment Opportunity Commission (EEOC) has stated that employers have the legal right to mandate employees to get a COVID-19 vaccine. Specifically, employers are entitled and required to ensure a safe workplace in which "an individual shall not pose a direct threat to the health or safety of individuals in the workplace." Requiring a COVID-19 vaccine will not violate the American Disabilities Act (ADA).

Further the EEOC has stated that "Simply requesting proof of receipt of a COVID-19 vaccination is not likely to elicit information about a disability and, therefore, is not a disability-related inquiry. However, subsequent employer questions, such as asking why an individual did not receive a vaccination, may elicit information about a disability and would be subject to the pertinent ADA standard that they be 'job-related and consistent with business necessity.'"

For more information on EEOC guidelines, please see their [website](#).

70) Where does it say that vaccines under EUA cannot be required?

It is stated in the provision section [360bbb-3 \(e\)\(1\)\(A\)\(ii\)\(III\) of the Food and Cosmetic Act – 21 U.S.C. 564](#), "Authorization for medical products for use in emergencies," which says:

(e)Conditions of authorization

(1)Unapproved product

(A)Required conditions

With respect to the [emergency use](#) of an [unapproved product](#), the Secretary, to the extent practicably given the applicable circumstances described in subsection (b)(1), shall for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(ii)Appropriate conditions designed to ensure that individuals to whom the product is administered are informed -

(III)***of the option to accept or refuse administration of the product***, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risk.

71) Will personal information of those vaccinated in North Dakota be shared with the federal government?

No. North Dakota refused to submit identifiable data to the federal government regarding who is vaccinated with COVID-19 vaccine. The NDDoH will only be sharing de-identified data with the federal government.

72) Is North Dakota a pilot state for COVID-19 vaccine?

North Dakota was one of five sites selected to participate as a planning pilot site for COVID-19 distribution. North Dakota was able to assist federal partners in planning for when COVID-19 vaccine will eventually be available. Planning topics included vaccine storage and handling, distribution, communications, information technology, data, etc. The Tribes and other partners, including pharmacies, were included in this planning process to ensure that they were able to provide valuable insight into COVID-19 vaccine planning and eventual distribution and administration.

North Dakota will **NOT** receive COVID-19 vaccine before other states.

73) Will vaccination rates be posted by priority groups? (ex. Vaccination rates for healthcare workers, long-term care residents, or teachers)

No. Vaccination rates are not available by priority group or profession. It is unlikely the NDDoH will be able to provide vaccination rates by priority groups, as this information is not reported through the NDIIS. Additionally, the NDDoH will not be reporting vaccination rates for staff and residents of nursing homes or for places of employment, such as schools.

Additional information about COVID-19 vaccine is available on [CDC's COVID-19 vaccine website](#).